



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

08/786,937	01/22/97	BOUCHARD	P 235299/96001
------------	----------	----------	----------------

CUSHMAN DARBY AND CUSHMAN
NINTH FLOOR EAST TOWER
1100 NEW YORK AVENUE NW
WASHINGTON DC 20005-3918

HM12/0711

EXAMINER

DELACROIX MUIRHEI, C

ART UNIT

PAPER NUMBER

1614

DATE MAILED:

07/11/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
---------------	-------------	-----------------------	---------------------

EXAMINER

ART UNIT	PAPER NUMBER
----------	--------------

19

Below is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

DATE MAILED:

ADVISORY ACTION

■ THE PERIOD FOR RESPONSE

- a) ☒ is extended to run _____ or continues to run 4 months from the date of the final rejection.
b) ☐ expires three months from the date of the final rejection or as to the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response as set forth in b) above.

☐ Appellant's Brief is due in accordance with 37 CFR 1.192(a).

☒ Applicant's response to the final rejection, filed May 9, 2000, has been considered with the following effect, but is not deemed to place the case in condition for allowance.

1. ☐ The proposed amendments to the claim/and or specification will not be entered and the final rejection stands because:

- a. ☐ There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.
b. ☐ They raise new issues that would require further consideration and/or search. (See note).
c. ☐ They raise the issue of new matter (See note).
d. ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
e. ☐ They present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE:

2. ☐ Newly proposed or amended claims ____ would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.

3. ☒ Upon the filing of an appeal, the proposed response ☒ will be entered ☐ will not be entered and the status of the claims will be as follows:

Claims allowed: None

Claims objected to: None

Claims rejected: 15, 16, 18-24, 26-33

However;

☐ Applicant's response has overcome the following rejection(s):

4. ■ The affidavit, exhibit or request for reconsideration has been considered, but does not overcome the previous rejection of claims 21, 22 and 33 under 35 U.S.C. 102(b) over Diedrich et al. and the previous rejection of claims 15, 16, 18-24, 26-33 under 35 U.S.C. 103(a) over Diedrich et al. in view of Felberbaum et al. for reasons given previously in the prior office actions.

With respect to the claims rejection under 35 USC 102(b), Applicants essentially argue, in the remarks received May 9, 2000, that Diedrich et al. do not anticipate the claimed method which requires (1) administration of .25 mg/day of Cetrorelix in a multiple dose regime or (2) administration of 3 mg of Cetrorelix in a single or dual dose. Said argument has been considered but is not found to be persuasive. Applicants are arguing limitations that are not present in claims 21, 22 and 33. Therefore, said arguments are not commensurate in scope with the claimed method.

Concerning the claims rejection under 35 USC 103(a), Applicant reiterates previously submitted arguments concerning the declaration of Nov. 23, 1998 and additionally argues that the prior art does not disclose administering "preferably" 3 mg Cetrorelix on cycle day 6 in single or dual doses. The prior art also does not disclose administration of .25 mg of Cetrorelix beginning in cycle day 6 in a multiple dose posology.

Applicants' arguments have been considered but are not found to be persuasive. Applicants' remarks with respect to the declaration do not appear to resolve the issues raised by the Examiner in the previous office actions (March 3, 1999 and Aug. 18, 1999). Moreover, the arguments concerning the dosage amounts have been addressed earlier in the office actions mailed March 3, 1999; Aug. 18, 1999 and Feb. 1, 2000. Accordingly, said rejection stands.

The previous provisional obviousness-type double patenting rejection set forth in paragraphs 4-5 of the office action mailed Aug. 18, 1999 is maintained until receipt and approval of a Terminal Disclaimer.

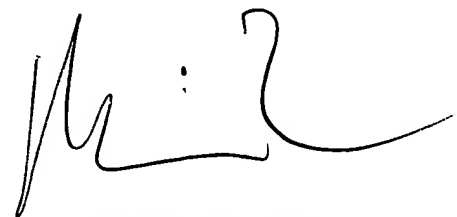
The previous provisional double patenting rejection under 35 USC 101, set forth in paragraphs 6-7 of the office action mailed Aug. 18, 1999 is maintained. Said rejection is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

5. ☐ The affidavit or exhibit will not be considered because applicant has not shown good and sufficient reasons why it was not earlier presented.

☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.

☐ Other



MARIANNE M. CINTAS
SUPERVISORY PATENT EXAMINER
GROUP 120